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Certifier D. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N–0042]

RIN 0910–AA01

Anticaries Drug Products for Over-the-Counter Human Use; Use of Intraoral Appliance Models for Compliance With Biological Testing Requirements; Request for Information and Comments; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until July 12, 2002, the comment period on the notice requesting information and comments on the use of intraoral appliance (IOA) models as a substitute for the animal caries reduction biological test required by the monograph for over-the-counter (OTC) anticaries drug products to demonstrate the availability of fluoride in OTC dentifrice formulations. The notice was published in the **Federal Register** of October 15, 2001 (66 FR 52418). FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to submit comments and information on the use of IOA models. The comment period for this information closed on January 14, 2002.

DATES: Submit written or electronic comments by July 12, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Robert L. Sherman, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2001 (66 FR 52418), FDA published a notice requesting information and comments regarding use of the IOA test in lieu of animal caries studies to demonstrate the effectiveness of new fluoride formulations. FDA issued this notice to gather information concerning IOA models and whether and how they can be used in lieu of the animal caries models in meeting the biological testing requirements for OTC anticaries drug products. The agency has determined that it is appropriate to address these issues in a public forum where experts can debate the usefulness and acceptability of alternate biological testing methods such as the IOA model. The agency anticipates that this information-gathering process will be followed by an advisory committee meeting at which the various models and the appropriate statistical analyses will be discussed.

On November 14, 2001, the Joint Anticaries Task Group (the Task Group) of the Consumer Healthcare Products Association, a trade association of manufacturers of nonprescription drugs and dietary supplements, and the Cosmetic, Toiletry, and Fragrance Association, a trade association of manufacturers of personal care products, requested a 180-day extension in which to file comments and new information (Ref. 1). The request stated that the closing date for the original comment period would not allow the Task Group to utilize the results of its ongoing research in its response to FDA, resulting in important information being omitted from the agency's consideration. In addition, the Task Group noted that the agency's request raises complicated questions concerning statistical approaches that could potentially impact statistical methodology utilized for current biological testing requirements for fluoride dentifrices. The Task Group also stated that manufacturers need sufficient time to assess the potential impact that the agency's

statistical questions may have on manufacturing practices, as well as research and product development.

FDA has carefully considered the request and acknowledges the complicated issues concerning statistical approaches used to evaluate IOA testing and their potential affect on current biological testing requirements of the anticaries monograph. Manufacturers and the Task Group may require additional time to obtain and review information to fully respond to the agency's request. FDA considers an extension of time for comments in this case to be in the public interest. Accordingly, the comment period is reopened to July 12, 2002.

II. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this notice by July 12, 2002. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT11, Docket No. 80N–0042.

Dated: 3/1/02

March 1, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

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